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RESEARCH ARTICLE

Drug Compliance among Type 2 Diabetic patients in Jazan Region, Saudi Arabia.

Taha Alhazmi, Jaber Sharahili, Shadi Khurmi, Turki Zughbi, Mariam Alrefai, Mohammed Hakami, Fahad Wasili, Mamdouh S. Wadani, Albaraa Sahli, Abdulrahman H. Alhazmi,
Sattam Jaddoh

Faculty of Medicine, Jazan University.

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Abstract

Background: Although adherence to prescribed medications is a key dimension of healthcare quality, there is no information about the magnitude of compliance of the diabetic patients in Jazan region of Saudi Arabia. **Objectives:** The purpose of this study is to measure the rate of adherence and the factors contributing to compliance among the diabetic patients in Jazan region. **Methods:** A total of 273 Type 2 diabetic patients who fulfill the inclusion criteria were recruited in the study. Adherence to the treatment was evaluated during patients' attending to the usual appointment in the randomly selected Primary Health Care centers and Diabetic Centers in Jazan region. The medication adherence was assessed during a personal interview using the 8-item Morisky Medication Adherence Scale (MMAS-8). **Results:** Twenty Three Percent of patients reported good medication adherence, 38.8 % medium adherence and 37.6 % poor medication adherence. The factors significantly associated with adherence in univariate analysis were socio-demographic factors: residence ($p = 0.02$) and distance from the health care center ($p = 0.023$); disease and health care related factors: Regularly attending to the appointments ($p = 0.038$) and HbA1c > 8 ($p = 0.06$). **Conclusion:** The findings indicate that there is a high rate of non-compliance among the diabetes patients in Jazan region of Saudi Arabia and there is a definite need for improvement in the healthcare system, health education, and training of diabetic patients.

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Introduction:-

Diabetes mellitus (DM) is a group of metabolic diseases characterized by hyperglycemia resulting from defects of insulin secretion and/or increased cellular resistance to insulin. Chronic hyperglycemia and other metabolic disturbances of DM lead to long-term tissue and organ damage as well as dysfunction involving the eyes, kidneys, and nervous and vascular systems. [1]

Diabetes is a serious condition with potentially devastating complications that affects all age groups worldwide. In 1985, an estimated 30 million people around the world were diagnose with diabetes; in 2000, that figure rose to over 150 million, and it is projected to rise further to 380 million by 2025. The International Diabetes Federation states

that “everyten seconds, two people are diagnosed with diabetes somewhere in this world,” and given the current trend, more people will have diabetes in 2025 than the current populations of the United States, Canada and Australia combined. [2]

In the Eastern Mediterranean Region, there has been a rapid increase in the incidence of DM, consisting mainly of Type 2 (T2DM). Much of this increase occurs in developing countries and results from population ageing, unhealthy diet, obesity and a sedentary lifestyle. It is now the fourth leading cause of death in this region. [3]

A key dimension of healthcare quality is adherence to prescribed medications. According to the World Health Organization (WHO), adherence is the extent to which a person’s behavior – taking medication, following a diet, and/or executing lifestyle changes – corresponds with agreed recommendations from the health care provider. However, medication non-adherence is particularly common among patients with type 2 diabetes and inadequate adherence compromises safety and treatment effectiveness, leading to increased mortality and morbidity with considerable direct and indirect costs to the healthcare system. A recent WHO report states that, because the magnitude of non-adherence and the scope of its sequelae are so alarming, more health benefits worldwide would result from improving adherence to existing treatments than by developing new medical treatments [4]

Clinical experience confirms, however, that despite the availability of increasingly modern and effective methods of treatment at least half of the patients fail to achieve satisfactory therapy goals and that non-compliance is believed to be the most common cause of treatment failures. After several decades of research, it was concluded that medication non-adherence is due to many factors including lack of adequate knowledge about medication and treatment goals, beliefs about the medication, complex regimens that are difficult to manage, side effects, and costs associated with medications [5][6].

There are several types of non-adherence. Therapeutic or medication non-adherence which includes failure to have the prescription dispensed or renewed, omission of doses, errors of dosage, incorrect administration, errors in the time and frequency of administration, and premature discontinuation of the drug regimen. A second type of non-adherence is dietary/exercise non-adherence in which the patient fails to follow the diet and exercise recommendations. A third type is the appointment non-adherence in which the patient fails to show up at the clinics for the scheduled check up. The consequences of medication non-adherence may not only be dangerous for patient’s health, but also dramatically increase the financial costs of public health services [7][8]

There are several methods are used to measure therapeutic adherence. Indirect methods, like self reports and interviews with patient, are the simplest and most common methods for measuring medication adherence (Girerd et al) . Pill counts method is also used to assess compliance in medical drug trials, by measuring the difference between the number of doses initially dispensed and the number remaining in the container. The achievement of treatment goals might also be used to assess compliance, especially when the drug therapy is associated with a successful outcome like normal blood pressure, or blood glucose levels. Computerized compliance monitors are the most recent and reliable methods, like the Medication Event Monitoring System (MEMS). The system consists of microprocessor placed in the cap of the medication container, every time the patient removes the cap, the time and date are recorded. Direct methods like measuring drug concentration or biological markers in the patients’ biological fluids, could also be used to assess compliance. Of the various methods used to assess compliance, none is without disadvantages [9]

Few studies about patient adherence to OHAs in Arab Countries have been published. Most of these studies were carried out in Saudi Arabia. One study was performed at Al-Manhal primary health care center, aimed at identifying determinants of compliance among diabetic patients attending that clinic (Khattab et al., 1999). Other study has been conducted in Al Hasa region aiming to estimate the magnitude of the problem of non-compliance and explore the factors contributing to non-compliance of the diabetic patients [10]. A recent study was performed to gather data on current practices in the management of patients with T2DM in Saudi Arabia and to evaluate the degree of compliance with international guidelines (AIEIq,2009 <http://www.ncbi.nlm.nih.gov/pubmed/19936419#>).

To the best of our knowledge, there is little or no information on the magnitude of compliance of the diabetic patients in the Jazan region of Saudi Arabia. For this purpose we conducted this research study whose aim to investigate the variability in the rate of medication adherence among Type 2 diabetic patients. This may lead to a clear understanding about poor glycemic control among these patients as well as for a strict

and successful management of this chronic illness in the future.

Study Objective:-

To measure the rate of compliance and the factors contributing to compliance among the diabetic patients in Jazan region, Saudi Arabia.

Specific Objectives:

- 1- To measure the rate of compliance among the diabetic patients.
- 2- To determine the role of demographic and clinical features to patients Compliance.
- 3- To Identify the diseases and health-care characteristics that is contributing to Patients compliance.

Patients and Methods:-

This was a cross-sectional survey. Patients with diabetes were interviewed during their attending to the usual appointment in the PHCs and diabetes centers.

Inclusion criteria were registered diabetic patients who were attending the selected clinics and were getting medication on a regular basis. Subjects with age more than 18 years and at least a one-year history of diabetes, and who were on a fixed drug therapy for the last six months, were selected for this study [11].

Sampling:- Since the population proportion is not known so it considered as 50 % with 95% confidence intervals which is not more than $\pm 5\%$ of true population proportion. The required sample size was 267 with 6% error. Two stages Cluster random sampling based on provinces and districts adopted to select the PHCs and Diabetic centers.

Data Collection:-

Patients who attended their regular appointments were interviewed using a structured questionnaire addressing the following aspects:

- (i) socio-demographic characteristics.
- (ii) health-care related factors,
- (iii) Disease and drugs related factors.
- (iv) assessment of patient adherence to medication using the 8-item Morisky Medication Adherence Scale (MMAS-8), translated into Arabic.

The MMAS-8 contains eight questions with closed dichotomous (yes / no) answers, designed to prevent the bias of positive response from patients questions asked by health professionals, by reversing the responses related to the interviewee's adherence behavior. Thus, each item measured a specific adherence behavior, with all questions must be answered negatively.

The degree of adherence was determined according to the score resulting from the sum of all the correct answers:

- High adherence (8 points)
- Average adherence (6 to < 8 points)
- Non-adherence (< 6 points)

In this study, patients was considered adherent when they had a score equal to eight in the MMAS-8 [12]

Data Analysis:-

The data obtained from the questionnaire were analyzed using **SPSS** for Windows, Version 17. Techniques involved **descriptive statistics** like frequency and percentage, and **inferential** statistics like Chi square test and logistic regression were used to analyze the significant associations between adherence rate and the and some selected factors. P-value < **0.05** was determined as significance.

Results :

Patients who satisfied the inclusion criteria were 237, 88.8% of the required sample. The **social-demographic** characteristics chosen in this study of the selected group of patients and their data, see Table 1.

Table 1: Socio-demographic characteristics of 237

Demographic Characteristic		Number	%
Gender	Male	156	65.8
	Female	81	34.2
Age	18-40	45	19.1
	41-60	110	46.6
	>60	81	34.3
Residence	City	99	41.8
	Village	138	58.2
Education	Uneducated	93	39.2
	Elementary	44	18.6
	Intermediate	23	9.7
	Secondary	18	7.6
	Higher Education	59	24.9
Marital Status	Single	12	5.1
	Married	202	85.2
	Divorced	5	2.1
	Widowed	18	7.6
Occupation	Student	5	2.1
	Employee	79	33.3
	Freelancer	13	5.5
	Retired	59	24.9
	Unemployed	81	34.2
Family income	Low	36	15.2
	Medium	166	70
	High	35	14.8

The majority of the participants were uneducated (39.2%, n = 93). Most were married (85.2%, n = 202).

There were 79% treated with OHA without insulin, most of them were taking medications for different diseases (45.6%, n = 108), for clinical characteristics chosen in this study of patients and their data, see Table 2

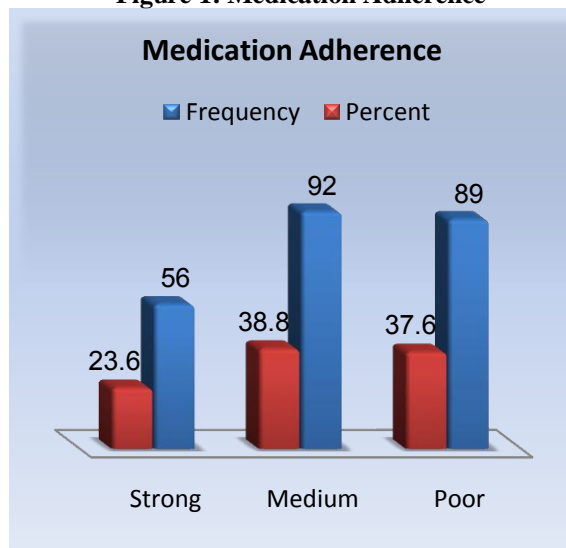
Table 2: Clinical characteristics of 237 responders. N (%)

Clinical characteristic		Total	Male	Female
Duration of the Disease	<2 years	24 (10.1)	15 (62.5)	9 (37.5)
	2-5 years	56 (23.6)	37 (66.1)	19 (33.9)
	>5 years	157 (66.3)	104 (66.2)	53 (33.8)
Treatment	OHA	135 (57)	100 (74.1)	35 (25.9)
	Insulin +/- OHA	102 (43)	56 (54.9)	46 (45.1)
Dosage	Once a day	26 (11)	19 (73.1)	7 (26.9)
	> once daily	210 (89)	137 (65.2)	73 (34.8)
Drugs	Monotherapy	48 (20.2)	34 (70.8)	14 (29.2)

	Combined therapy	81 (34.2)	61 (75.3)	20 (24.7)
	Drugs for deferent diseases	108 (45.6)	61 (56.5)	47 (43.5)
Hypertension	No	134 (56.8)	95 (70.9)	39 (29.1)
	Yes	102 (43.2)	60 (58.8)	42 (41.2)
CHD	No	216 (91.5)	142 (65.7)	74 (34.3)
	Yes	20 (8.5)	13 (65)	7 (35)

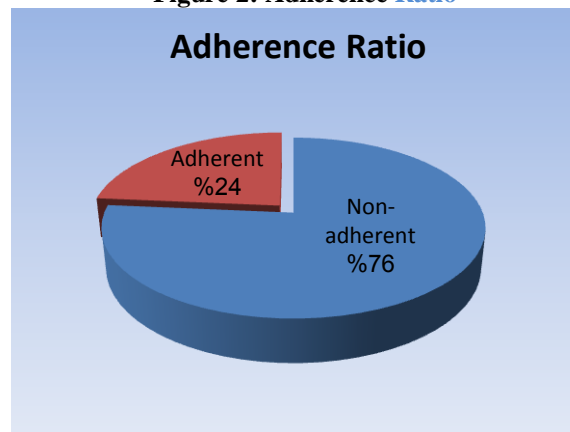
Twenty Three Percent of patients reported good medication adherence, 38.8% medium adherence and 37.6 % poor medication adherence. figure 1

Figure 1: Medication Adherence



So, as Adherent, Non-adherent prevalence, it was very high ratio as shown in figure 2 below.

Figure 2: Adherence Ratio



The non-adherence in the urban participants was significantly higher than in the rural participants (87.9 vs. 68.1%, P=0.02).

People those were living near the centers showed high rate of non-adherence (80.3 vs 63.2%, P=0.023) than those who live far. The non adherence was significantly higher in the patients they were not regularly attending their appointment than those who were regularly attending (88.1 vs. 72.2% P=0.038) . see Table 3

Gender and duration since diagnosis did not affect medication adherence (P=0.74, 0.70 respectively) . see Table 3

No significant association found between adherence and type of treatment (P=0.31) or between poor-adherence and number of dosage taken by patients (P=0.6). see Table 3

Seventy percent of poor adherence show low glycaemic control according to HbA1c test (>8%), see figure 3

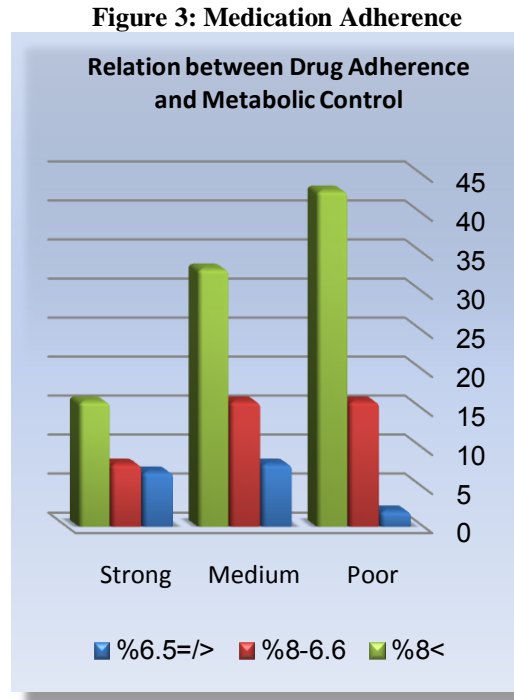


Table 3: Association between **medication adherence** and some selected **demographic** and **clinical** characteristics, MMAS-8 (N = 237)

Variables		P-value	MMAS-8 Adherence						Total	
			Strong		Medium		Poor			
			N	%	N	%	N	%		
<i>Demographic Variables</i>										
Gender	Male	0.748	35	22.4	60	38.5	61	39.1	156	
	Female		21	25.9	32	39.5	28	34.6	81	
Age	18-40	0.109	11	24.4	10	22.2	24	53.3	45	
	41-59		25	22.7	47	42.7	38	34.5	110	
	>60		20	24.7	34	42	27	33.3	81	
Residence	City	0.02	12	12.1	46	46.5	41	41.4	99	
	Village		44	31.9	46	33.3	48	34.8	138	
Education	Uneducated	0.325	19	20.4	35	37.6	39	41.9	93	
	Elementary		14	31.8	18	40.9	12	27.3	44	
	Intermediate		5	21.7	11	47.8	7	30.4	23	
	Secondary		1	5.6	7	38.9	10	55.6	18	
	Higher Education		17	28.8	21	35.6	21	35.6	59	
Marital Status	Single	0.284	1	8.3	5	41.7	6	50	12	
	Married		46	22.8	78	38.6	78	38.6	202	
	Divorced		1	20	3	60	1	20	5	
	Widowed		8	44.4	6	33.3	4	22.2	18	
Occupation	Student	0.287	1	20	0	0	4	80	5	
	Employee		19	24.1	31	32.2	29	36.7	79	
	Freelancer		1	7.7	4	30.8	8	61.5	13	
	Retired		13	22	23	39	23	39	59	
	Unemployed		22	27.2	34	42	25	30.9	81	
Family income	Low	0.826	6	16.7	14	38.9	16	44.4	36	
	Medium		42	25.3	64	38.6	60	36.1	156	
	High		8	22.9	14	40	13	73.1	35	
Distance from HCC	Near	0.023	34	19.7	67	38.7	72	41.6	173	
	Far		21	36.8	20	35.1	16	28.1	57	
<i>Clinical Variables</i>										
Duration of the Disease	<2 years	0.703	8	33.3	8	33.3	8	33.3	24	
	2-5 years		12	21.4	20	35.7	24	42.9	56	
	>5 years		36	22.9	64	40.8	57	36.3	157	
Treatment	OHA	0.318	27	20	55	40.7	53	39.3	135	
	Insulin +/- OHA		29	28.4	37	36.3	36	35.3	102	
Dosage	Once a day	0.661	7	26.9	8	30.8	11	42.3	26	
	> once daily		49	23.3	84	40	77	36.7	210	
Drugs	Monotherapy	0.332	14	29.2	19	39.6	15	31.3	48	
	Combined therapy		14	17.3	30	37	37	45.7	81	
	Drugs for deferent diseases		28	25.9	43	39.8	37	34.3	108	
Hypertension	No	0.621	30	22.4	50	37.3	34	40.3	134	
	Yes		Before DM	8	19.5	15	36.6	18	43.9	41
			After DM	19	31.1	27	44.3	15	24.6	61
CHD	NO	0.21	49	22.7	83	38.4	84	38.9	216	
	Yes		7	35	9	45	4	20	20	
Hb1c	Strong ≤ 6.5	0.068	7	41.2	8	47.1	2	11.8	17	
	Medium 6.6-8		8	20	16	40	16	40	40	
	Poor >8		16	17.4	33	35.9	43	46.7	92	
Committing to the Appointment	No	0.02	7	11.9	21	35.6	31	52.5	59	
	Yes		49	27.8	69	39.2	58	33	176	

Discussion:-

The control of diabetes is crucially dependent on the diabetic patient's compliance to medical advice [13]. compliance of diabetic patients is a complex issue. This study explored therapeutic adherence and the factors contributing to the adherence of diabetic patients in Jazan region.

Non adherence with medication in this study was similar to the earlier finding in Egypt [7], Palestine [10], France [4], Poland [14] and Saudi Arabia [11]

In Palestine study, non-compliance was divided into two categories (51.4 % poor compliance and 6.5 % non-compliance) [10]. In France the non-compliance was divided into two categories also (49% medium adherence and 12% poor adherence) [4].

In the Saudi study, which conducted in Al Hasa region they found that the therapeutic non-compliance of the participants was 67.9% [11].

There was a significant rural–urban difference in the non-compliance rate among the diabetic patients in this study. The non-compliance in the urban population was significantly higher than the rural population (87.9 vs. 68.1%, $P=.02$). The same finding has been documented in the Saudi and Palestine study where the non-compliance among urban diabetic patients was higher than among the rural patients (71.04 vs. 60.15%, $P = .023$) for Saudi study and (8.2 vs. 6.2%, $P = .003$) for the study conducted in Palestine, This difference may be due to various lifestyles. Urban residents tend to be more sedentary with relatively poor dietary habits as compared to the rural population [10][11]

In this study, no significant difference in adherence was found between males and females, The effect of gender on the rate of adherence to medication in other research studies is contradictory. Female patients were found by some researchers to have better adherence [15] while some studies suggested otherwise [16]. In addition, some studies could not find a relationship between gender and adherence to medication, this difference may be due to geographical variation in their education, and social factors [7].

This study showed a significant association between poor-adherence and attending to the appointments, patients they were not regularly attending their appointments have a high rate of poor-adherence than those attending their appointments regularly (88.1 vs. 72.2% $P=0.038$).

The same result has found in the Saudi study, Patients who were regular on follow- up had a significantly higher compliance rate than those who were irregular (46.88% for those who never missed an appointment, 35.53% for those who had missed an appointment once or twice in a year, 26.40% for those who had missed the appointment more than twice in a year and 18.19% for those who never attended the clinic, $P=.039$) [11].

In the researches that published earlier, they found that the most important causes of Poor adherence with clinic appointments were the non-availability of transport, followed by forgetfulness. Forgetfulness has been widely published as an important cause of irregularity of follow-up. Besides, owing to socio-cultural factors females cannot go out on their own to a health care center [11].

Patients with poor adherence showed low glycaemic control (HbA1c >8) and this is similar to the results found in other researches [4].

We didn't find any significant association between poor-adherence and level of education. Some studies have found the same result. while other's studies have found an association between lower education level and poor adherence. A study conducted in UK shown that patients with a lower level of education have better compliance. It may be presumed that patients with a lower educational level may have more trust in the physician's advice. However, these results show that education may not be a good predictor of therapeutic Adherence [11].

Results showed no significant association between poor-adherence and type of treatment or number of dosages.

This results similar to that's conducted in French [4], in contrast to the Saudi study that's found non-adherence was least with the single drug regimen while it was highest among patients who were on combined oral and insulin treatment [11].

Conclusion:-

Medication adherence is vital for effective diabetes management. The study results showed that the rate of non-adherence of diabetic patients in Jazan region was high.

Attending the appointments regularly played an important role in medication adherence, so we suggest that there is a need to establish some sort of system by which contact can be made with those patients who have difficulty in attending clinics and medication delivered to them on time.

Since patients showed more committing to their appointment in diabetic centers than in PHC, although they usually farther because they are more advanced facilities, more caring and have a better and specialized staff, they give them the relief, trust and more willing to follow the medical advice, so we suggest that the diabetic centers should be enhanced and take the major of the diabetic patients care system.

For the improvement with medication adherence Physician–patient relationship as well as patient’s knowledge of diabetes should be improved through proper educational and training programs

Although this study is the first of its type in Jazanregion , it has some limitations

- Time : since we had to complete this study just in three weeks because of modules schedule of the college.
- Small sample size.
- The study used only one method to assess compliance.

Our recommendations for future works are to use validated adherence measures, e.g., Computerized compliance monitors like the Medication Event Monitoring System (MEMS) and to run other methods concurrently for assessment of therapeutic adherence, e.g pill counts for a comparison study. Moreover, it is very important to conduct a research on larger sample population and from different clinical settings and areas.

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